PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
RLL-249WO		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 03/01416	15.04.2003	15.04.2002

International Patent Classification (IPC) or both national classification and IPC
A61K9/20, A61K9/20

Applicant
RANBAXY LABORATORIES LIMITED

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.11.2003	07.06.2004

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/01416

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-30 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 29 and 30 with respect to industrial applicability

because:

☒ the said international application, or the said claims Nos. 29 and 30 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	17, 22-24, 27
	No:	Claims	1-16, 18-21, 25, 26, 28-30
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-30
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 29 and 30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents are referred to:

D1: US 6,306,436 B (cited in the application)
D2: US 6,033,686 A
D3: EP 1 020 184 A

1 - Clarity

It is clear from the description on page 6, lines 19-26 that the method of manufacturing the tablets, i.e. by dry granulation (see examples and claim 12) is essential for the definition of the invention.

Since independent claims 1 and 29 do not contain this feature it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

At present, the subject-matter of claims 1 and 29 merely amounts to stating (one of) the result(s) to be achieved by the application, namely to provide stable tablets of bupropion HCl.

2 - Novelty

1 - Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of claims 1-16, 18-21, 25, 26 and 28-30 is not new in the sense of Article 33(2) PCT.

2 - It is to be noted that the phrase "free of stabilizer" (claims 1, 28 and 29) cannot be taken into account for the judgement of novelty. The word "stabilizer" is a functional term which can only be read as a compound which stabilizes the tablet. In the absence of any further definition this means that in fact any compound in a (stable) tablet could be regarded as a "stabilizer", rendering the phrase "free of stabilizer" as used in the claims contradictory and meaningless.

Furthermore, the tablets of the examples all contain stearic acid, which is a carboxylic

acid and hence a "stabilizer", judging from the list in the paragraph bridging pages 7 and 8.

3 - Document D1 (column 6, lines 34-48; examples; claims) discloses stable sustained release tablets of bupropion HCl which are "free from added acid". The tablets are prepared by direct compression. D1 is considered to preclude the novelty of claims 1-9, 29 and 30.

4 - Document D2 (column 3, lines 30-39; examples; claims) discloses coated controlled release tablets of bupropion HCl, which are "free of stabilizer" but nevertheless stable. Thus claims 1-5, 9-11, 29 and 30 lack novelty over D2.

5 - Document D3 (par. 9; par. 21-23; example 1; claims) discloses stable sustained release tablets comprising bupropion HCl, which are prepared by dry granulation. Though the tablets of D3 comprise sodium bisulfate as a stabilizer, as explained above the feature "free of stabilizer" (claims 1, 28 and 29) cannot be seen as a distinguishing feature. Hence claims 1-5, 9-16, 18-21, 25, 26 and 28-30 lack novelty over D3.

6 - The subject-matter of claims 17, 22-24 and 27 appears to be novel.

3 - Inventive Step

1 - Lacking novelty, the subject-matter of claims 1-16, 18-21, 25, 26 and 28-30 cannot be seen as involving an inventive step (Article 33(3) PCT).

2 - The incorporation of the additional features contained in dependent claims 17, 22-24 and 27 into the corresponding independent claim does not result in subject-matter which would be considered as involving an inventive step, because said features are not described as being related to a particular technical effect and, therefore, represent only trivial modifications (Article 33(3) PCT).

4 - Industrial Applicability

The subject-matter of claims 1-28 is considered to meet the requirements of Article 33(4) PCT (see also Item III above).